IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARBUTUS BIOPHARMA CORPORATION and GENEVANT SCIENCES GmbH,	)	
Plaintiffs,	)	C.A. No. 22-252 (JDW)
v.	)	
MODERNA, INC. and MODERNATX, INC.	)	
Defendants.	)	

MODERNA'S BRIEF IN SUPPORT OF ITS PARTIALLY OPPOSED MOTION TO SEAL

MORRIS, NICHOLS, ARSHT & TUNNELL LLP
Brian P. Egan (#6227)
Travis J. Murray (#6882)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
began@morrisnichols.com
tmurray@morrisnichols.com

Attorneys for Defendants

OF COUNSEL:

James F. Hurst
KIRKLAND & ELLIS LLP
333 West Wolf Point Plaza
Chicago, IL 60654
(312) 862-2000

Patricia A. Carson, Ph.D.
Jeanna M. Wacker, P.C.
Leslie M. Schmidt, P.C.
Mark C. McLennan
N. Kaye Horstman
Shaoyao Yu
Mara L. Greenberg
Andrew Lee
Brad Deem
KIRKLAND & ELLIS LLP
601 Lexington Avenue
New York, NY 10022
(212) 446-4679

Jason M. Wilcox, P.C.
KIRKLAND & ELLIS LLP
1301 Pennsylvania Avenue, N.W.
Washington, D.C. 20004
(202) 389-5000

Noah Frank
Alina Afinogenova
KIRKLAND & ELLIS LLP
200 Clarendon Street
Boston, MA 02116
(617) 385-7500

Yan-Xin Li
Hannah Suh
Laura Ashley Harris
KIRKLAND & ELLIS LLP
555 California Street, 27th Floor
San Francisco, CA 94104
(415) 439-1400

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I. INTRODUCTION

Pursuant to the Protective Order (D.I. 91) as modified by the Court's November 14, 2023 Order (D.I. 155) and the Court's August 19, 2025 Order (D.I. 545), Defendants Moderna, Inc. and ModernaTX, Inc. ("Moderna") respectfully move this Court for an order granting leave to file partially redacted versions of the following documents filed by Plaintiffs: (a) Plaintiffs' Sur-Reply Brief in Support of Plaintiffs' Cross-Motion for Summary Judgment ("Plaintiffs' Sur-Reply MSJ"); (b) Plaintiffs' Reply Affirmative Statement of Uncontested Facts in Support of Their Cross-Motion for Summary Judgment ("Plaintiffs' Statement"); (c) Plaintiffs' Reply in Support of Motion to Exclude Certain Expert Testimony of Rutherford, Vellturo, and Prud'homme, and Opposition to Motion to Exclude Certain Testimony of Mitchell ("Plaintiffs' Reply MTE"); (d) Exhibit 122 (Rebuttal Expert Report of Dr. Owen Shea Fenton); (e) Exhibit 123 (Rebuttal Expert Report of Dr. Robert Prud'homme); (f) Exhibit 124 (Opening Report of Dr. Michael Mitchell); (g) Exhibit 126 (Method Development Data); (h) Exhibit 130 (April 28, 2025 Deposition Transcript of Dr. Daniel Anderson); (i) Exhibit 132 (April 30, 2025 Deposition Transcript of Dr. Michael Mitchell); and (j) Exhibit 140 (Reply Expert Report of Dr. Daniel Anderson) (collectively, the "Redacted Reply and Sur-Reply Filings").[1] As explained in more detail below, the portions marked for redaction contain Moderna's sensitive and confidential technical information, including sensitive and proprietary manufacturing, clinical development, testing and lipid component information of its COVID-19 Vaccine and prior formulations.

[1] All other exhibits are filed publicly. In accordance with Section I.D.2 of the Court's Policies and Procedures, the sealed versions of the Redacted Reply and Sur-Reply Filings highlight the portion that Moderna proposes to redact. Redactions were also applied to portions of certain exhibits to redact information not relevant to the parties' motions.

In support of this motion, Moderna attaches as Exhibit A the Declaration of Brian Doyle, a Senior Director of Technical Development at ModernaTX, Inc. since September 2023. Previously, Mr. Doyle was a Director of Technical Development from March 2021 to September 2023 and an Associate Director from June 2020 to March 2021. Mr. Doyle also served as a Principal Scientist from March 2019 to June 2020. In these roles, Mr. Doyle is familiar with Moderna's clinical product development, including development, testing, and manufacturing of lipid nanoparticle ("LNP") products. Mr. Doyle is familiar with the fact that Moderna maintains this information as confidential and is familiar with the extensive efforts Moderna takes to protect its confidential information. As supported by Mr. Doyle, Moderna seeks to seal limited portions of the Redacted Reply and Sur-Reply Filings.

Plaintiffs have indicated that they oppose redactions to information regarding fractionation testing (Plaintiffs' Sur-Reply MSJ, Plaintiffs' Statement, and Exhibits 126, 132, and 140) and to references to the molar ratios or changes to the molar ratios in Moderna's vaccine (Exhibit 124). Plaintiffs represented to Moderna that their bases for opposing Moderna's redactions are the same as what Plaintiffs included in their last opposition brief. Plaintiffs do not oppose the remainder of the redactions that Moderna proposes in this Motion.

All of the Redacted Reply and Sur-Reply Filings, as explained by Mr. Doyle, contain Moderna's highly confidential information, and the Court should maintain that material under seal in order to prevent serious and real harm to Moderna. Release of Moderna's highly confidential information to the public and Moderna's competitors would create a clearly defined and serious injury to Moderna, as discussed in detail below.

II. LEGAL STANDARD

Third Circuit common law presumes a public right of access to judicial records; however, it also protects business and financial information when access would cause economic harm,

including competitive harm. *In re Avandia Mktg., Sales Pracs. & Prod. Liab. Litig.*, 924 F.3d 662, 672 (3d Cir. 2019). "Although the common law right to public access is a recognized and venerated principle, courts have also recognized the accompanying principle that the right is not absolute." *In re Cendant Corp.*, 260 F.3d 183, 194 (3d Cir. 2001) (citations and quotations omitted); *see also Littlejohn v. Bic Corp.*, 851 F.2d 673, 678 (3d Cir. 1988) ("Despite the presumption, courts may deny access to judicial records, for example, where they are sources of business information that might harm a litigant's competitive standing.").

This presumption is overcome where a movant shows "that the interest in secrecy outweighs the presumption." *In re Avandia Mktg.*, 924 F.3d at 672 (quoting *Bank of Am. Nat'l Tr. & Sav. Ass'n v. Hotel Rittenhouse Assocs.*, 800 F.2d 339, 344 (3d Cir. 1986)). This showing may be made by demonstrating that disclosure will work a clearly defined and serious injury to the movant and that the material is the kind of information that courts will protect. *See In re Avandia Mktg.*, 924 F.3d at 672 (citing *Miller v. Indiana Hosp.*, 16 F.3d 549, 551 (3d Cir. 1994)). The Court will apply a "good cause" standard justifying sealing or redacting judicial records, requiring a "balancing process, in which courts weigh the harm of disclosing information against the importance of disclosure to the public." *Mosaid Techs. Inc. v. LSI Corp.*, 878 F. Supp. 2d 503, 507-08 (D. Del. 2012) (citing *Pansy v. Borough of Stroudsburg*, 23 F.3d 772, 787 (3d Cir. 1994)).

III. BACKGROUND

Significant competition exists among biopharmaceutical companies researching, testing, and developing LNPs for mRNA-based products. Ex. A at ¶ 17. Additionally, there are companies considering entering the vaccine market and companies developing mRNA-based vaccines and therapeutics for other diseases or developing LNPs for mRNA-based products that would be at a strategic advantage if Moderna's proprietary formulation and ratio of ingredients became public. *Id.* Because there are so few competitors in these markets, the markets are highly competitive,

and any information about one of the competitors, even seemingly minor information, may prove competitively advantageous. *Id.* As described by Mr. Doyle, a competitor with access to Moderna's confidential formulations could redirect its research budget away from basic formulation discovery and toward incremental improvements or differentiation strategies, giving it a material head start. *Id.* Moderna has spent significant resources to develop its formulation, and the release of such information to the public, including Moderna's competitors, would significantly harm Moderna. *Id.*

Moderna would be substantially harmed if its competitors became aware of this highly confidential and trade secret information that Moderna has tested and developed as competitors would save significant time, in some cases potentially months or years, of testing that Moderna had to spend developing its own proprietary formulations, manufacturing processes, and analytical techniques. Ex. A at ¶ 18. Disclosure would also result in substantial competitive harm where competitors would be able to replicate Moderna's proprietary formulations, analytical processes, and manufacturing processes. *Id.* The harm from disclosure would be immediate and substantial. For example, a competitor developing a vaccine or therapeutic in the same class could use Moderna's confidential data to quickly identify which specific formulations, manufacturing processes, and analytical tests are most effective, allowing them to shorten their development timelines by months or years. This would not only erase Moderna's competitive advantage but could also jeopardize Moderna's ability to negotiate favorable business partnerships, as collaborators and licensees would perceive Moderna's proprietary information as less secure. *Id.*

As will be discussed on a document-by-document basis, the information that Moderna intends to keep sealed includes very specific concentrations of lipid components, molar ratios, proprietary encapsulation processes, and assay methods. This information is highly confidential

and trade secret information that Moderna has taken extensive efforts to keep non-public. The development of these processes and techniques required years of research, testing, and optimization by multi-disciplinary teams at Moderna. *Id.* at ¶ 5. Disclosure of this information would not only reveal the "successful" processes Moderna relies upon today but also enable competitors to avoid failed or abandoned approaches that Moderna already tested at significant cost. In effect, disclosure would allow competitors to "leapfrog" years of scientific trial-and-error. *Id.*

IV. ARGUMENT

Good cause exists here to seal the Redacted Reply and Sur-Reply Filings because they contain Moderna's highly confidential technical information. Disclosure of such information would cause real and serious competitive harm to Moderna, and the information does not need to be disclosed to the public to understand the filings at issue.

The information Moderna seeks to seal in Plaintiffs' Sur-Reply MSJ, Plaintiffs' Statement, Plaintiffs' Reply MTE, and Exhibits 122, 123, 124, 126, 130, 132, and 140 relates to Moderna's clinical development, testing, research, and formulation of LNP products. Although the public's presumptive common law right of access to judicial records attaches to materials filed in connection with a pretrial motion of a non-discovery nature, this right is "not absolute" and may be overcome by a showing that the material sought to be sealed "is the kind of information that courts will protect and . . . will work a clearly defined and serious injury to the party seeking closure." *In re Avandia Mktg.*, 924 at 672 (citation omitted). Here, the redacted information in the Redacted Reply and Sur-Reply Filings are all the types of limited information of the kind that courts in the Third Circuit have recognized as protectable, namely highly sensitive and confidential technical information regarding Moderna's proprietary and trade secret formulation, manufacturing, methods, development, and testing of its COVID-19 Vaccine. *See*

D.I. 546 at 7, 9 ("[I]nformation relating to the development, testing, and formulation of Moderna's LNP products is likely a trade secret. . . . I will permit Moderna to redact information in the filings that relates to the molar ratios of its vaccine products"); *see also Aptiv Techs., Ltd. v. Microchip Tech. Inc.*, C.A. No. 23-307-JDW, D.I. 163, at 2-3 (D. Del. Apr. 1, 2024) ("Proprietary technical information is a type of information that courts protect.").

Moderna has always taken extensive measures to maintain the confidentiality of its technical information. Ex. A at ¶ 6. Moderna has been extremely concerned about the protection of its confidential information during this litigation and has been very careful to always protect this information. *Id.* This information is of the type that courts have recognized as protectable. *See, e.g.*, *Nitto Denko Corp. v. Hutchinson Tech. Inc.*, C.A. No. 16-3595 (CCC/MF), 2017 WL 2782639, at *2 (D.N.J. Mar. 3, 2017) (granting motion to seal "confidential technical information" where such information "was not intended to be seen by competitors . . . for review and potential use against the parties," and parties were in a "highly competitive [] industry"); *Guardant Health, Inc. v. Found. Med., Inc.*, C.A. No. 17-1616-LPS-CJB, D.I. 447 (D. Del. June 16, 2020) (granting motion to redact confidential information concerning defendant's confidential technical information).

Disclosure of Moderna's confidential information regarding either the technical details of Moderna's formulation and researching, testing, and developing of LNPs for mRNA-based products would "work a clearly defined and serious injury" to Moderna. As such, disclosure would provide Moderna's competitors, customers, and potential licensors or licensees with otherwise confidential information regarding Moderna's products and strategies, as well as a competitive advantage in both the vaccine supplier market and in negotiations with Moderna. *See Pansy*, 23 F.3d at 786. Moreover, because this "case involves private litigants" and their

confidential information, there is "little legitimate public interest" in the proposed redactions. *Id.* at 788. Under such circumstances, Moderna's interest in maintaining the confidentiality of the proposed redacted information outweighs any countervailing public interest. *See id.* ("[I]f a case involves private litigants, and concerns matters of little legitimate public interest, that should be a factor weighing in favor of granting or maintaining an order of confidentiality."); *Leucadia, Inc. v. Applied Extrusion Techs., Inc.*, 998 F.2d 157, 166 (3d Cir. 1993) ("Documents containing trade secrets or other confidential business information may be protected from disclosure" and explaining that the court has "framed the inquiry as whether the need for secrecy outweighs the presumption of access that normally attaches to such documents"); *Nixon v. Warner Commc'ns, Inc.*, 435 U.S. 589, 598 (1978) ("[C]ourts have refused to permit their files to serve as . . . sources of business information that might harm a litigant's competitive standing"); *SmartSky Networks, LLC v. Gogo Bus. Aviation, LLC*, C.A. No. 22-266-JDW, D.I. 487, at 3 (D. Del. Mar. 11, 2025) (granting motion to seal because "[t]he market is small and highly competitive, so competitors would likely exploit and benefit from this sort of technical information. The Parties have articulated a specific harm that would come from making this information public, they have supported the request with Declarations rather than just arguments of counsel, and their request is narrowly tailored to the information that would work such a competitive harm.").

Moderna seeks only to partially seal the confidential materials at issue. This narrow scope of redactions will not inhibit the public's ability to understand the record, and the record will not be impaired any more than necessary to prevent the release of Moderna's most sensitive technical information to its potential competitors, preventing clear competitive harm.

Finally, Judge Goldberg and Your Honor have maintained under seal similar highly confidential proprietary information. *See* January 2, 2024 Order (D.I. 178) (granting motion to

seal (i) the composition of Moderna's COVID-19 vaccine which indirectly references the quantities of the components, which Moderna maintains as confidential, and (ii) regulatory submissions disclosing specific information concerning Moderna's proprietary and trade secret manufacturing methods for its COVID-19 vaccine including steps in the manufacturing process and parameters for those steps); D.I. 546. The parties also agreed that proprietary information about their products, including the ratio of lipid components, should be treated as 'Confidential' under the agreed-upon Protective Order. D.I. 91 at 1.2(c).

A. Exhibit 122 Contains Highly Confidential and Trade Secret Information That Warrants Sealing

Exhibit 122 is an excerpt of the Rebuttal Expert Report of Dr. Owen Shea Fenton that contains highly confidential information about Moderna's proprietary LNP formulations, including information that would reveal specific manufacturing steps of Moderna's mRNA-LNP products, and there are no less restrictive means to redact this information besides sealing it completely. Ex. A at ¶ 7. The information in these paragraphs reflects the order and way in which components of Moderna's mRNA-LNP products are incorporated and combined, including specific concentrations of components and intermediaries that are not publicly known. *Id.* Moderna maintains that the specific manufacturing steps and order for adding LNP components is proprietary and a trade secret, only known to a limited number of personnel at Moderna, and exposure of this information to competitors after years of research and development could cause substantial harm to Moderna. *Id.* Even a small change in the steps or order of the steps can dramatically alter product-quality attributes. *Id.* Knowing such manufacturing process specifics would eliminate the need for competitors to experiment across dozens of permutations, saving them years of development. Moderna maintains that aspects of the encapsulation process are trade secret information, and Moderna's internal capabilities and testing are not publicly known. *Id.*

Even limited information could prove to be a competitive advantage to the limited number of competitors in the LNP product-development market and companies using mRNA-based treatments. Judge Goldberg and this Court have granted motions to seal similar types of Moderna's highly confidential and trade secret information. *See* D.I. 178 & D.I. 546 at 7, 9.

B. Paragraphs 441 and 442 of Exhibit 123 Contain Highly Confidential and Trade Secret Information That Warrants Sealing

Exhibit 123 is an excerpt of the Rebuttal Expert Report of Dr. Robert Prud'homme. Portions of Paragraphs 441 and 442 contain highly confidential and proprietary information surrounding Moderna's manufacturing process of its LNP products. This information should be redacted for the same reasons as described above with respect to Exhibit 122, including because this information is closely guarded and reflects extensive research and development by Moderna scientists. Even a small change in the steps or order of the steps can dramatically alter product quality attributes. Knowing such manufacturing process specifics, would eliminate the need for competitors to experiment across dozens of permutations, saving them years of development. Paragraph 442 also reveals the name of Moderna's LNP, which, in context, reveals important information regarding Moderna's trade secret manufacturing process. Ex. A at ¶ 8. Certain terms—such as the names of lipid classes or a general reference to the name of Moderna's LNP—may appear in the public domain. However, the confidentiality of such terms depends heavily on the surrounding context in which they appear. When such terms appear in combination with descriptions of manufacturing processes and parameters, including process steps and sequences, equipment and/or other LNPs, such disclosures reveal Moderna's proprietary formulation strategy and manufacturing know-how. In other words, it is not the word/term itself that is confidential, but the way that word is used in context with other non-public parameters. As used in Paragraph 442, the name of Moderna's LNP would reveal such confidential information,

potentially allowing competitors to reconstruct Moderna's internal development decisions and replicate Moderna's proprietary and sensitive LNP manufacturing processes. *Id.* Moderna's proposed redactions are limited to reflect only its highly confidential and trade secret information and do not inhibit the public's ability to understand the motion at issue. Judge Goldberg and this Court have granted motions to seal similar types of Moderna's highly confidential and trade secret information. *See* D.I. 178 & D.I. 546 at 7, 9.

C. Paragraphs 266, 267, 382–384, and 606 of Exhibit 124 Contain Highly Confidential and Trade Secret Information That Warrants Sealing

Exhibit 124 is an excerpt of the Opening Expert Report of Dr. Michael Mitchell. Page 4 of the Table of Contents and Paragraphs 266, 267, 382–384, 484–486, 604, and 606 contain Moderna's highly confidential information. Specifically, page 4 of the Table of Contents reveals the name of Moderna's LNP, which, in context, reveals important information regarding Moderna's trade secret manufacturing process. Ex. A at ¶¶ 8–9. Paragraphs 266, 267, 604, and 606 reveal concentrations and molar ratios of lipid components used in Moderna's product candidates and Moderna's COVID-19 vaccine. *Id.* at ¶ 9. Moderna maintains that the concentrations of its lipid components, and the resulting molar ratios of these lipid components, are proprietary. *Id.* This information is only known within a limited number of personnel at Moderna, and exposure to competitors after years of research and development could cause substantial harm to Moderna. Although some drug product labels for Moderna's COVID-19 vaccine have included information reflecting the weight of certain components, the specific concentrations provided in Paragraphs 266, 267, 604, and 606 are more precise and could be used by competitors to develop similar LNP formulations. *Id.* Paragraphs and 382–384, 484, and 604 contain highly confidential information concerning Moderna's proprietary manufacturing process and should be redacted for the same reasons as described above with respect to Exhibit

122. Paragraphs 485 and 486 contain highly confidential information about assays used by Moderna to determine mRNA encapsulation, one of which is a proprietary assay developed by Moderna and is not publicly known. Moderna's proposed redactions are limited to reflect only its highly confidential and trade secret information and does not inhibit the public's ability to understand the motion at issue. Judge Goldberg and this Court have granted motions to seal similar types of Moderna's highly confidential and trade secret information. *See* D.I. 178 & D.I. 546 at 7, 9.

D. Exhibit 126 Contains Highly Confidential and Trade Secret Information That Warrants Sealing

Exhibit 126 is a table reflecting LC-CAD data, which could be used to calculate specific lipid concentrations of certain lot numbers of Moderna's COVID-19 vaccine. Moderna maintains that the concentrations of its lipid components, and the resulting molar ratios of these lipid components, are proprietary. This information is only known within a limited number of personnel at Moderna, and exposure to competitors after years of research and development could cause substantial harm to Moderna. Ex. A at ¶ 10. Revealing this information to competitors after years of research and development could cause substantial harm to Moderna. *Id.* Although some drug product labels for Moderna's COVID-19 vaccine have included information on the weight amount of the components, the specific concentrations provided in Exhibit 126 are more precise and could be used by competitors to develop similar LNP manufacturing processes and products, resulting in harm if disclosed. Exhibit 126 should be sealed in its entirety as there is no less restrictive means to redact this highly confidential information.

E. Pages 34 and 35 of Exhibit 130 Contain Highly Confidential and Trade Secret Information That Warrants Sealing

Exhibit 130 is an excerpt from the April 28, 2025 Deposition Transcript of Dr. Daniel Anderson. Pages 34 and 35 of the transcript disclose highly confidential information about a

specific step in Moderna's manufacturing process that is a trade secret and should be sealed for the reasons discussed with respect to Exhibit 122. *See also* Ex. A at ¶¶ 7, 11. Lines 1–3 of the transcript refer to Dr. Anderson's experience with a specific way of manufacturing nucleic acid-LNPs, which, given the context of the surrounding questions and answers that focus on Moderna, would reveal aspects of Moderna's confidential and trade secret manufacturing method and should therefore be sealed as well. *Id.* at ¶ 11. Judge Goldberg and this Court have granted motions to seal similar types of Moderna's highly confidential and trade secret information. *See* D.I. 178 & D.I. 546 at 7, 9. Moderna's proposed redactions are limited to a few lines on pages 34 and 35 that reflect its highly confidential and trade secret information, and the redactions do not inhibit the public's ability to understand the motion at issue.

F. Pages 125–129, 133–135, 144–146, and 150 of Exhibit 132 Contain Highly Confidential Information and Should Be Sealed

Exhibit 132 is an excerpt from the April 30, 2025 Deposition Transcript of Dr. Michael Mitchell. Pages 125–129, 133–135, 144–146, and 150 contain highly confidential information concerning the lipid molar concentrations in Moderna's LNP products. Moderna maintains that the concentrations of its lipid components, and the resulting molar ratios of these lipid components, are proprietary and only known to a limited number of personnel at Moderna. Exposure of this information to competitors after years of research and development could cause substantial harm to Moderna. Ex. A at ¶ 12. Although some drug product labels for Moderna's COVID-19 vaccine have included information on the weight amount of the components, the specific concentrations provided in this transcript are more precise and could be used by competitors to develop similar LNP manufacturing processes and products and its parameters and would result in harm if disclosed. *Id.* Judge Goldberg and this Court have granted motions to seal similar types of Moderna's highly confidential and trade secret information. *See* D.I. 178 & D.I.

546 at 7, 9. Moderna's proposed redactions are limited to a few lines that reflect its highly confidential information, and the redactions do not inhibit the public's ability to understand the motion at issue.

G. Paragraphs 284 and 285 of Exhibit 140 Contain Highly Confidential and Trade Secret Information That Warrants Sealing

Exhibit 140 is an excerpt of the Reply Expert Report of Dr. Daniel Anderson. Portions of Paragraphs 284 and 285 contain highly confidential and proprietary information surrounding Moderna's manufacturing process of its LNP products. Ex. A at ¶ 13. This information should be redacted for the same reasons as described above with respect to Exhibit 122, including because this information is closely guarded and reflects extensive research and development by Moderna scientists. Even a small change in the steps or order of the steps can dramatically alter product quality attributes. Knowing such manufacturing process specifics, would eliminate the need for competitors to experiment across dozens of permutations, saving them years of development. Moderna's proposed redactions are limited to reflect only its highly confidential and trade secret information and do not inhibit the public's ability to understand the motion at issue. Judge Goldberg and this Court have granted motions to seal similar types of Moderna's highly confidential and trade secret information. *See* D.I. 178 & D.I. 546 at 7, 9.

H. Page 7 of Plaintiffs' Sur-Reply MSJ and Page 16 of Plaintiffs' Reply MTE Contain Highly Confidential and Trade Secret Information That Warrants Sealing

Page 7 of Plaintiffs' Sur-Reply MSJ and Page 16 of Plaintiffs' Reply MTE contain highly confidential and proprietary information surrounding Moderna's manufacturing process of its LNP products. Ex. A at ¶¶ 14, 16. This information should be redacted for the same reasons as described above with respect to Exhibit 122, including because this information is closely guarded and reflects extensive research and development by Moderna scientists. Even a small change in the

steps or order of the steps can dramatically alter product quality attributes. Knowing such manufacturing process specifics, would eliminate the need for competitors to experiment across dozens of permutations, saving them years of development. Moderna's proposed redactions are limited to reflect only its highly confidential and trade secret information and do not inhibit the public's ability to understand the motion at issue. Judge Goldberg and this Court have granted motions to seal similar types of Moderna's highly confidential and trade secret information. *See* D.I. 178 & D.I. 546 at 7, 9.

I. Paragraphs 30, 32, 35, 57, 87, and 92 of Plaintiffs' Statement Contain Highly Confidential and Trade Secret Information That Warrants Sealing

Paragraphs 30, 32, 35, and 87 of Plaintiffs' Statement contain highly confidential and proprietary information surrounding Moderna's manufacturing process of its LNP products. Ex. A at ¶ 15. This information should be redacted for the same reasons as described above with respect to Exhibit 122, including because this information is closely guarded and reflects extensive research and development by Moderna scientists. Even a small change in the steps or order of the steps can dramatically alter product quality attributes. Knowing such manufacturing process specifics, would eliminate the need for competitors to experiment across dozens of permutations, saving them years of development. Paragraph 57 contains highly confidential information concerning the outcome of characterization of Moderna's LNPs using techniques like digestion assays and dye exclusion assays, the results of which Moderna maintains as proprietary and confidential. Should these characterization results become public, competitors would be made aware of certain characteristics of Moderna's LNPs and could use these characteristics to develop their own LNPs, resulting in harm to Moderna. *Id.* Paragraph 92 contains highly confidential information concerning the lipid molar concentrations of Moderna's LNP products, which could be used to calculate specific lipid concentrations of certain lot numbers of Moderna's COVID-19

vaccine. Moderna maintains that the concentrations of its lipid components, and the resulting molar ratios of these lipid components, are proprietary. *Id.* This information is only known within a limited number of personnel at Moderna, and exposure to competitors after years of research and development could cause substantial harm to Moderna. *Id.* Although some drug product labels for Moderna's COVID-19 vaccine have included information reflecting the weight of certain components, the specific concentrations provided in Plaintiffs' Statement are more precise and could be used by competitors to develop similar LNP formulations, resulting in harm if disclosed. *Id.*

Moderna's proposed redactions are limited to reflect only its highly confidential and trade secret information and do not inhibit the public's ability to understand the motion at issue. Judge Goldberg and this Court have granted motions to seal similar types of Moderna's highly confidential and trade secret information. *See* D.I. 178 & D.I. 546 at 7, 9.

J. The Lipid Molar Ratios Moderna Seeks to Seal Are Not Publicly Available and Should Remain Sealed

Plaintiffs have indicated that they oppose redacting references to the molar ratio of Moderna's products, discussions of changes to Moderna's formulations, redactions to lipid molar ratios and lipid concentrations, and testing techniques to determine lipid molar concentrations. At the outset, Moderna notes that this Court has already found such information confidential, warranting sealing, notwithstanding Plaintiffs' opposition. Plaintiffs seek to relitigate the same issue by opposing Moderna's redactions of this same information without providing any new basis to do so. As explained throughout this motion and below, the information Moderna seeks to redact is not public and would create significant harm if publicly disclosed.

1. The Lipid Ratios and Lipid Amounts Moderna Seeks to Seal are Not Already Publicly Known

Moderna disagrees with Plaintiffs' suggestion that much of Moderna's LNP product information, particularly concerning the molar ratios of its vaccine products, is already public. First, while Moderna has patents describing various molar ratios, that does not tell the public which of the various ratios in those patents Moderna uses for its target molar ratios in each of its various commercial products. While Moderna has disclosed that certain products in specific preclinical and clinical trials have used a lipid molar ratio of 50:10:38.5:1.5, Moderna has not disclosed the lipid molar ratio of ***all*** products that it has been developing, or of ***all*** formulations (including lipid molar ratios) that Moderna has used in various preclinical and clinical studies. Second, Plaintiffs allege that Moderna's actual molar ratios could be reverse engineered, but if this were so easy, then the allegations in Plaintiffs' own complaint would not have identified the incorrect target molar ratios in the commercial formulations of Moderna's COVID-19 vaccine. *See* D.I. 1 ¶¶ 45, 49, 76, 95, 114, 137, 179 (identifying the purported target ratio in Moderna's COVID-19 vaccine). Third, with respect to certain public drug-product labels, as explained in Mr. Doyle's declaration, although some drug-product labels for Moderna's COVID-19 vaccine have included information on the weight amount of the components, the specific concentrations provided in the exhibits Moderna seeks to seal are more precise, relevant to specific LNP manufacturing processes and parameters, are not public, and would result in harm if disclosed. Ex. A at ¶¶ 9, 10, 12, 14, 15, 19. Fourth, even if certain molar ratios are public, such as the target lipid molar ratio used in preclinical studies which Moderna does not seek to redact, this does not justify publicly revealing all target and actual molar ratios for all Moderna products. These types of harm should be protected against by maintaining confidential information under seal. *See*

Nixon, 435 U.S. at 598; *SmartSky Networks*, C.A. No. 22-266-JDW at D.I. 487; *Nitto Denko*, 2017 WL 2782639, at *2.

2. Plaintiffs Consistently Agreed Lipid Ratios and Lipid Content of Formulations Were Confidential Trade Secrets that Warranted Sealing

At the outset of this case, the parties explicitly agreed that the lipid molar ratios used in Moderna and ***Plaintiffs'*** products are to be treated as 'CONFIDENTIAL' under the Protective Order because such information was "generally not known" and "would not normally [be] reveal[ed] to third parties." D.I. 91 at ¶ 1.2 ("CONFIDENTIAL" Material means . . . information or material not generally known and which the Producing Party would normally not reveal to third parties, including but not limited to" . . . "the lipid molar ratio of the Accused Products and the lipid molar ratio of products developed or licensed ***by Plaintiffs***"). To be clear, Moderna does not submit that this Protective Order provision that Plaintiffs stipulated to *alone* shows the information is entitled to remain under seal, but it directly contradicts Plaintiffs' new position three years into this lawsuit that lipid molar ratios are generally considered public knowledge. Plaintiffs previously argued in a motion to seal that the "quantities of ingredients" in its ***own*** products were "not public knowledge" and considered "trade secret information" worthy of sealing. D.I. 186 at 9, 10 ("Plaintiffs have spent significant effort and resources to develop these manufacturing methods and formulations and the release of such information to the public, including Plaintiffs' competitors, would ***harm Plaintiffs***"), D.I. 186 Ex. B., ¶12 ("Plaintiffs consider ***precise LNP formulations, including the quantities*** and types of ingredients used, and related stability and specification data trade secret, which is not public knowledge"), and D.I. 186, Ex. 24 (Plaintiffs proposing redactions to lipid molar ratios).

Plaintiffs' new position that lipid molar ratios are generally considered public knowledge also appears to be a gambit to escape the negotiated prosecution bar for this matter, which

prevents those with access to the other party's "CONFIDENTIAL" information, including the lipid molar ratios, from prosecuting patents. D.I. 91 at ¶¶ 1.2, 7.1. There is a very real risk of harm to Moderna if its non-public formulations are publicly disclosed without the protections of the prosecution bar entered in this case. Indeed, Moderna's derivation defense for the '651 patent relies on evidence that Plaintiffs filed that patent seeking for the first time to claim mRNA formulations several months after Plaintiffs, and the named inventors, monitored Moderna's patent filings. D.I. 567, Ex. 62 to McLennan Declaration at 436–438; D.I. 559, Moderna's Response to Plaintiffs' Statement of Facts at ¶¶ 216–219. *In re Deutsche Bank Tr. Co. Americas*, 605 F.3d 1373, 1380 (Fed. Cir. 2010) (in the context of a protective order dispute, recognizing the risks of providing access to those "making strategic decisions on the type and scope of patent protection that might be available or worth pursuing for such inventions, writing, reviewing, or approving new applications or continuations-in-part of applications to cover those inventions, or strategically amending or surrendering claim scope during prosecution"). If Moderna's sensitive lipid molar ratios are not maintained under seal, the entire public would have access to that information, including Plaintiffs, who tout their hundreds of patents and applications. D.I. 569, Ex. 79 to McLennan Declaration at 8712, 731–735, and 736 ("Genevant continues to innovate, files and prosecutes LNP patent families to further bolster its dominant position,").

V. CONCLUSION

For the foregoing reasons, Moderna respectfully requests that the Court grant Moderna's Motion to Seal with respect to Moderna's highly confidential information in the Redacted Reply and Sur-Reply Filings.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Travis J. Murray

Brian P. Egan (#6227)
Travis J. Murray (#6882)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
began@morrisnichols.com
tmurray@morrisnichols.com

Attorneys for Defendants

OF COUNSEL:

James F. Hurst
KIRKLAND & ELLIS LLP
333 West Wolf Point Plaza
Chicago, IL 60654
(312) 862-2000

Patricia A. Carson, Ph.D.
Jeanna M. Wacker, P.C.
Leslie M. Schmidt, P.C.
Mark C. McLennan
N. Kaye Horstman
Shaoyao Yu
Mara L. Greenberg
Andrew Lee
Brad Deem
KIRKLAND & ELLIS LLP
601 Lexington Avenue
New York, NY 10022
(212) 446-4679

Jason M. Wilcox, P.C.
KIRKLAND & ELLIS LLP
1301 Pennsylvania Avenue, N.W.
Washington, D.C. 20004
(202) 389-5000

Noah Frank
Alina Afinogenova
KIRKLAND & ELLIS LLP
200 Clarendon Street
Boston, MA 02116
(617) 385-7500

Yan-Xin Li
Hannah Suh
Laura Ashley Harris
KIRKLAND & ELLIS LLP
555 California Street, 27th Floor
San Francisco, CA 94104
(415) 439-1400

September 23, 2025

CERTIFICATE OF SERVICE

I hereby certify that on September 23, 2025, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on September 23, 2025, upon the following in the manner indicated:

John W. Shaw, Esquire — *VIA ELECTRONIC MAIL*
Karen E. Keller, Esquire
Nathan R. Hoeschen, Esquire
Emily S. DiBenedetto, Esquire
SHAW KELLER LLP
I.M. Pei Building
1105 North Market Street, 12th Floor
Wilmington, DE 19801
Attorneys for Plaintiffs Arbutus Biopharma Corporation and Genevant Sciences GmbH

Daralyn J. Durie, Esquire — *VIA ELECTRONIC MAIL*
Adam R. Brausa, Esquire
Eric C. Wiener, Esquire
Annie A. Lee, Esquire
Shaelyn K. Dawson, Esquire
MORRISON & FOERSTER LLP
425 Market Street
San Francisco, CA 94105-2482
Attorneys for Plaintiff Arbutus Biopharma Corporation

Kira A. Davis, Esquire — *VIA ELECTRONIC MAIL*
MORRISON & FOERSTER LLP
707 Wilshire Boulevard
Los Angeles, CA 90017-3543
Attorneys for Plaintiff Arbutus Biopharma Corporation

David N. Tan, Esquire
MORRISON & FOERSTER LLP
2100 L Street, NW, Suite 900
Washington, DC 20037
Attorneys for Plaintiff Arbutus Biopharma Corporation

VIA ELECTRONIC MAIL

David I. Berl, Esquire
Adam D. Harber, Esquire
Thomas S. Fletcher, Esquire
Shaun P. Mahaffy, Esquire
Andrew L. Hoffman, Esquire
Matthew W. Lachman, Esquire
Ricardo Leyva, Esquire
Arthur J. Argall III, Esquire
Falicia Elenberg, Esquire
Kathryn Larkin, Esquire
WILLIAMS & CONNOLLY LLP
680 Maine Avenue S.W.
Washington, DC 20024
Attorneys for Plaintiff Genevant Sciences GmbH

VIA ELECTRONIC MAIL

Andrei Iancu, Esquire
Jeffrey B. Wall, Esquire
SULLIVAN & CROMWELL LLP
1700 New York Avenue, N.W., Suite 700
Washington, DC 20006
Attorneys for Plaintiff Genevant Sciences GmbH

VIA ELECTRONIC MAIL

/s/ Travis J. Murray

Travis J. Murray (#6882)